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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,949	03/26/2002	Lorenzo Piccone	1303-138	4722
7590	06/02/2004		EXAMINER	
Nixon & Vanderhye 8th Floor 1100 North Glebe Road Arlington, VA 22201-4714				LAYNO, CARL HERNANDZ
		ART UNIT		PAPER NUMBER
		3762		6

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/070,949	PICCONE, LORENZO
	Examiner	Art Unit
	Carl H. Layno	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 March 2002.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-18 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 26 March 2002 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/13/2002</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Acknowledgment is made of applicant's preliminary amendments, which were received by the Office on March 13, 2002 and on May 15, 2002. These documents have been made of record in the file as Paper Nos. 1 and 5, respectively.
2. Claims 17 and 18 have been added. Claims 1-18 are active.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

4. Acknowledgment is made of applicant's Information Disclosure Statement (PTO-1449) which was received by the Office on March 13, 2002.

Drawings

5. Applicant's formal drawings were received by the Office on March 13, 2002 and have been approved by both the Draftsperson and the Examiner.

Specification

6. The disclosure is objected to because of the following informalities:

-The specification sections lack appropriate headers, as per MPEP §608.01. See below:

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. *Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading.* If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

-Specifically, applicant's application is lacking section headings for sections (f), (g), and (h). The Examiner also suggests changing the heading "Purpose of the Invention" to "Field of the Invention" and changing the heading "Basis of the Invention" to "Background of the Invention".

-In addition the following typographical errors were noted in the specification:

-p.5, line 21, the word "shies" should be spelled "series", and

-p.6, line 3, the word “shies” should be spelled “series”.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to claim 1, line 2, the acronym “VEGF” is indefinite since it has not been previously defined. To resolve this ambiguity, the examiner recommends replacing this acronym with the words “Vascular Endothelial Growth Factor (VEGF)”.

In regard to claim 5, the statement “said means designed to transmit the said pulses” has no antecedent basis in this claim or in base claim 1. To overcome this rejection, the Examiner recommends changing the word “transmit” to “apply”.

In regard to claim 8, line 1, there is no antecedent basis for an “Apparatus for anti-inflammatory treatment” in claim 1.

In regard to claim 10, line 1, there is no antecedent basis for an “Apparatus for the activation of the microcirculation” in claim 1.

In regard to claim 11, line 3, there is no antecedent basis for the “up/down circuit”.

In regard to claim 14, the statements “a shies of electrical pulses” (line 3) and “trough electrodes” (p.16, line 1) makes no sense. To overcome this rejection, the Examiner recommends changing the word “shies” to the word “series”, and changing the word “trough” to the word “through”.

In regard to claim 16, line 1, the acronym “VEGF” is indefinite since it has not been previously defined. To resolve this ambiguity, the examiner recommends replacing this acronym with the words “Vascular Endothelial Growth Factor (VEGF)”. In addition, the words “shies” (line 3) and “trough” (line 6) appear to be typographical errors. To correct these deficiencies, the Examiner recommends changing the word “shies” to the word “series”, and changing the word “trough” to the word “through”.

Allowable Subject Matter

9. Claims 1-18 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

10. The following is a statement of reasons for the indication of allowable subject matter:

The claims, as written, recite an apparatus and method steps, respectively, detailing the generation of a series of electrical pulses specifically designed to promote production of Vascular Endothelial Growth Factors (VEGF) and/or may also be used to treat other muscle, tendon, and/or vascular disorders. These pulses have uniquely short pulse widths (7-12 nanoseconds) and are generated in bursts lasting 10-40 microseconds long with an intensity of 100-170 microamperes and a voltage of up to 220 volts. The Examiner could find no pulse generators for medically treating patients capable of producing series of therapeutic pulses having this claimed configuration for producing the unexpected beneficial results of increased VEGF production. Although applicants' prior art reference of Klotz '563 describes a pulse generator apparatus reading upon much of applicant's claimed features, it appears to be

incapable of producing series of pulses having applicant's claimed pulse widths, and; consequently, would be incapable of enhancing VEGF production in the manner claimed.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The Dev et al '247, Dimmer et al '558, and Henkens et al '558 patents are cited for their pertinent disclosures of external patient electrical stimulation devices having many of applicant's claimed features and are used for inducing vasodilation, treating muscle pain, and detecting DNA, respectively. Although Henkens et al and Dev et al refer to VEGF, neither enhances its production through electrical stimulation pulses in the manner of applicant's claimed device. None are capable of generating electrical signal pulses having widths of 7-12 nanoseconds, as claimed by the applicant.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (703) 308-3694. The examiner can normally be reached on Monday thru Thursday from 9 AM to 6 PM and every other Friday between 9AM and 5PM. A voice mail or E-mail message (carl.layno@uspto.gov) may be left if desired.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes, can be reached on (703) 308-5181. All faxed communications should be sent to the Office's new Official FAX number (703) 872-9306.

Art Unit: 3762

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Legal Instruments Examiner (LIE) Brenda Webb whose telephone number is (703) 305-7520.

Carl A. Layno

**CARL LAYNO
PRIMARY EXAMINER**

CHL
5/27/2004